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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,229	08/26/2003	Charles R Wescott	10280-077002	6199

26161 7590 03/30/2006

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EXAMINER

GUPTA, ANISH

ART UNIT PAPER NUMBER

1654

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/649,229	Applicant(s) WESCOTT ET AL.	
	Examiner Anish Gupta	Art Unit 1654	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-64 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 49-64 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11-12-04, 2/2/05, 1/5/05</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Procedural History

1. This Application is a continuation of 09/627,806. Applicants filed an amendment on 8-26-03 which canceled claims 1-48 and added new claims 49-64. Claims 49-64 are pending in this Application.

In the Parent Application, 09/627,806, a restriction requirement was under 35 U.S.C 121 which 274 groups. The 274 groupings set apart each of the various product types, such as polypeptides, polynucleotides, and bacteriophage. Within each product type a further restriction was required to a single sequence. Thus a single group corresponded to a single sequence identifier. For example, Group 14 corresponded to polypeptide comprising SEQ ID NO: 11 and Group 15 corresponded to polypeptide comprising SEQ ID NO 12, etc. . . It should be noted that the sequence identifier recited in the instant claims, correspond to the polypeptides restricted in the 274 group restriction in the parent application.

On June 21, 2002 Applicants filed a Petition pursuant to 37 C.F.R 1.181, in the Parent Application, to have the restriction requirement reviewed. In the Petition, Applicants admitted that the "polypeptides as claimed do not relate to independent and distinct invention" (see page 1, first paragraph of the Petition). Further, "[t]he fibrin binding polypeptides as disclosed and claimed by Applicants are not independent and distinct inventions" (see page 7, second full paragraph). Applicants stressed again on page 8 of the petition, "each separate polypeptide can hardly be regarded as distinct from all others claimed. . . .As disclosed, such similar polypeptides would not be separately patentable and thus cannot be considered distinct."

The Petition decision issued on September 13, 2002. The decision stated "[s]ince Applicant has elected a single polypeptide species for examination and has traversed this requirement in the

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petition on the grounds that the various polypeptide species are not patentably distinct, the restriction requirement between the various polypeptides is hereby withdrawn. The various polypeptides will be examined together. Since the examiner has already identified art that anticipates the first, second and third of the various polypeptides listed in the claims, applicants' admission presented in this petition may be used in a rejection under 35 U.S.C. 103(a) of the other invention, even if the claims are limited in scope as to exclude the first, second or third polypeptides."

It is again reiterated that the various polypeptides claimed in the instant application are identical to the various polypeptides claimed, that were at issue in the petition, in the parent application. This is because both sets of polypeptides have the same sequence identifiers.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 49-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have been amended to claim peptides that are cyclized through a disulfide bridge between two cysteine residues. The peptides as currently claimed sequences are identified by Sequence Identifier 1-2, 5-19, 20-29, 32-34, 40-43, 45-48, 51, 57-63 65, and 66. However, these sequence identifiers were used to identify the linear peptides in the parent application and thus the sequence identifiers used in this application as cyclic peptides do not have antecedent basis in the specification. In the parent Application, the sequence of SEQ ID 1, the sequence listing does not

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identify the disulfide bridge occurring through the cysteine residues. The MPEP states that in the sequence listing any peptide or protein that can be expressed as a sequence using the symbols in Appendix 2, Table 3, in conjunction with a description elsewhere to describe, for example, abnormal linkages, cross-links (for example, disulfide bridge) and end caps, non-peptidyl bonds, etc., is embraced by this definition. See MPEP 2401. Thus, since description was not given to the sequence identifiers to identify them as cyclic, the sequences identifiers in the parent are deemed to identify the linear peptides. Accordingly, using the sequence identifiers renders the sequence

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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3. Claims 49-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keates et al. in view of Wickstrom et al.

The claims are drawn to isolated polypeptides that are cyclized through a disulfide bridge.

Keates et al. teach the C-terminal fragment of mucin MUCB (see abstract). The reference specifically teaches the peptide CHFYAVC, which is amino acids 188-194, of the mucin peptide. This peptide corresponds to the peptide of formula of SEQ ID #2 in the specification on page 8 (see page 295-296 and 298). The difference between the prior art and the instant application is that the reference does not specifically disclose the peptide as claimed in the instant claims.

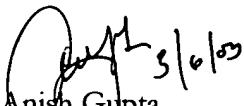
Wickstrom et al. teach that cysteine rich regions within the central super repeat region of MUC5B may be folded and stabilized by disulfide bonds (see page 692). Keates et al. teach that cysteine rich domain begins at amino acid 176 (see page 298 of Keates). Since disulfide bonds stabilize the cysteine rich region of MUC5B and the sequence CHFYAVC is within that region, one would expect the presence of di-sulfide bonds between amino acid 188 and 194.

Further, Applicants have admitted polypeptides “as claimed do not relate to independent and distinct invention” (see page 1, first paragraph of the Petition). Further, “[t]he fibrin binding polypeptides as disclosed and claimed by Applicants are not independent and distinct inventions” (see page 7, second full paragraph). “Each separate polypeptide can hardly be regarded as distinct from all others claimed. . . .As disclosed, such similar polypeptides would not be separately patentably and thus cannot be considered distinct.” Since Applicants have admitted on the record that the polypeptide claimed do not related to independent and distinct inventions, the polypeptides of the US patent renders obvious the other “various polypeptides.” Note that in the petition decision, the claims would be rendered obvious even if the claims are limited in scope as to exclude

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the first, second or third polypeptides. Here, even if Applicants have limited the polypeptides to the cyclic peptides, the admission in the petition renders obvious the claimed peptides.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (571)-273-8300.


Anish Gupta
Patent Examiner